Biomedical Adhesive, Surgical Textile and Hypodermic Needle Testing

This document is a collection of articles relating to the mechanical testing of adhesives, textiles, and needles used in medical applications. This document is intended to help you understand the basic procedures and equipment required to tests these devices. When you are ready to test your products or materials to specific standards, we recommend purchasing and referencing official ASTM or ISO publications.

Contents:

Articles

1. Medical Adhesive Testing Basics

From orthodontic bonding agents to wound closures, to gels for medical sensor pads, the term medical adhesive can refer to any product that is used to adhere or bond in a medical application. Medical adhesives can be categorized by application and adhesion method. Common applications include bandages, dental appliances, dental composites, wound closure, tissue repair, securing bone pins/screws, prosthetic assemblies and attachments, implants joints and connectors, medicinal patches, and medical sensor pads. The adhesion method refers to the way in which the adhesive is applied and the bond is activated. For example, pressure sensitive tapes (e.g. bandages) are bonded to the skin by applying pressure. Other medical adhesives, such as those used in dental applications, are activated by heat or UV light.

Medical adhesives can be tested for structural strength, adhesion properties, and environmental/ chemical resistance. Structural strength tests include measurements in tension/ compression and elongation. Examples of these tests in the medical field are the compressive load resistance of a plastic adhesive applied to a substrate (skin, ligament, muscle) or the elongation of self-adhering bandage wrap applied to a joint area.

Adhesion property tests include peel strength, bond strength, lap shear, tack strength, friction, and adhesive reusability. These tests are the most common and are relevant to almost every medical application. These tests determine how hard the adhesive is to apply and remove, how well it attaches to the substrate (skin, tissue, bone, implants, prosthetic devices, etc), and how long the product is able to maintain its adhesive properties (e.g. the reusability of a bandage).

Environmental/chemical resistance tests are used to measure the structural and adhesion properties of adhesives in different temperature, moisture, and chemical conditions. In medical applications, this normally refers to the human body. Through the use of temperature chambers and environmental baths, medical adhesive performance inside the human body can be simulated in vitro.

There are several ASTM and ISO testing standards that are relevant to medical adhesives. These include:

- ASTM D903 Peel or Stripping Strength of Adhesive Bonds
- ASTM D3330 Peel Adhesion of Pressure Sensitive Tape
- ASTM D1876 T-Peel Test
- ASTM D1002 Adhesive Lap Joint Shear Strength Test
- ASTM D6195 Adhesive Loop Tack Strength Test
- ASTM F2258 Tensile Strength of Tissue Adhesives
- ASTM F2458 Wound Closure Strength of Tissue Adhesives
- ASTM F2256 Strength Properties of Tissue Adhesive by T-Peel Loading

The equipment required to test medical adhesives will change depending on the test being performed. However, most medical adhesive tests will require:

- A servo-controlled (constant rate of motion) universal testing machine capable of tension/compression.
- A peel testing fixture (if performing an angled peel test).
- Grips and/or plates to secure the specimen (specimen defined as an adhesive and a substrate).
- A testing controller (software based or standalone) to control the testing machine actuator at the required rate and record/process test data (perform calculations and create testing reports).
- An environmental chamber or bath (optional).

ADMET has provided adhesive testing systems to leading medical device manufactures, universities and research laboratories. We offer a full line adhesive testing systems featuring constant-rate-of-extension (CRE) and constant-rate-of-load (CRL) control, allowing you to perform a wide variety of adhesive tests to ASTM or ISO standards. ADMET systems will automatically perform and report all needed calculations. Our wide range of fixtures, grips, and environmental chambers will accommodate nearly any application. Modifications to systems as well as custom fixtures can be designed for special applications.



2. Surgical Sutures and Mesh Testing Basics

The term Medical textile can be used to describe a wide range of products, including: gauze, bandages, medical clothing, and implantable biomaterials. This post refers specifically to the mechanical property testing of implantable mesh and sutures used in surgical applications.

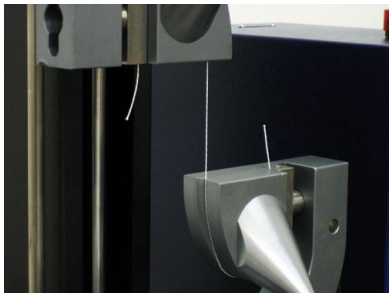
All products to be used in medical applications should be accurately tested during product development and manufacturing processes. Doing so helps to ensure patient safety and comfort and enables practitioners to perform medical procedures correctly. The need for comprehensive product testing is even greater for products used in surgical applications because of an added consideration, the need to know how these materials will react and interact with the human body, a factor known as biocompatibility.

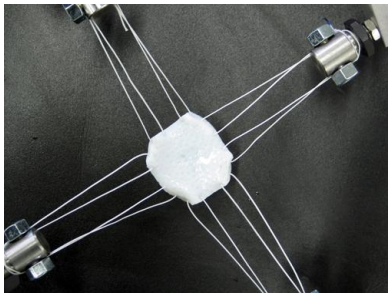
Sutures are used by doctors to stitch and hold together the structure of tissue. Sutures can be designed to biodegrade into the body or be removed after a certain period of time. Testing the tensile strength (measure of the average tensile load required to bring the material to a complete break) of sutures can help determine how likely the stitch is to break and the amount of stitch separation needed to hold tissue. Testing the elongation (average increase in length) of suture materials helps determine how likely the suture is to hold when stretched and the amount of pain the stitch can cause the patient when used in areas of high mobility. Planar biaxial (pulling of both axes simultaneously) and biaxial (tension plus torsion) tests can be conducted to further replicate the behavior of suture products in real world applications. To simulate how sutures will react inside the human body, these tests can be performed inside of temperature chambers and/or liquid baths. These tests can be performed on just the suture material (A) or on a sutured tissue sample (B).

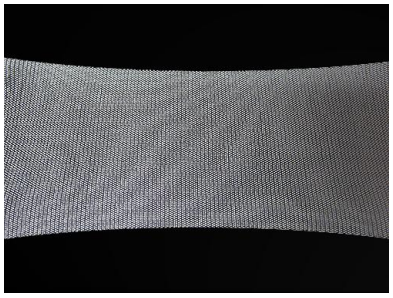
Surgical mesh is used to secure inner tissue walls in applications such as hernia repair. Like sutures, there are absorbable and non absorbable types of surgical mesh. Unlike sutures, surgical mesh is normally not removed and is almost always applied inside the body. Tension and elongation testing of the woven fibers should be performed to ensure structural integrity and durability. Planar biaxial (pulling of both axes simultaneously) and biaxial (tension plus torsion) tests can be conducted to further replicate the behavior of surgical mesh in real world applications. To simulate how surgical mesh will react inside the human body, these tests can be performed inside of temperature chambers and/or liquid baths.

ADMET offers a full line of testing systems to help you test surgical mesh and sutures with certainty. The following equipment is required to perform the tests described above:

- A machine frame and load cell capable of applying the amount of tensile force needed to bring the specimen to a full break.
- A testing controller capable of pulling the sample at a specified rate, identify peak load, and record test data.
- A pair of grips or fixture that is able to securely hold your specimen. Special rope/thread grips are recommended for sutures. Web/ribbon grips can be used for long samples of mesh. Vice grips, available in both manual and pneumatic configurations, can be used for mesh. Self-tightening eccentric roller grips can be used to secure certain types of sutures and mesh. Specialized fixtures are available for performing planar biaxial tests.
- A heating/cooling chamber and/or bath to simulate in-body product performance.







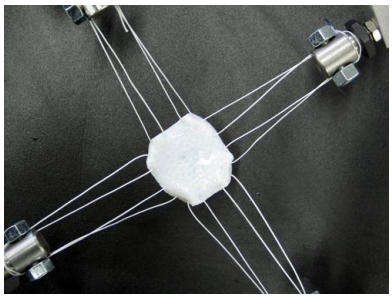
3. Planar Biaxial Testing of Biological Tissue

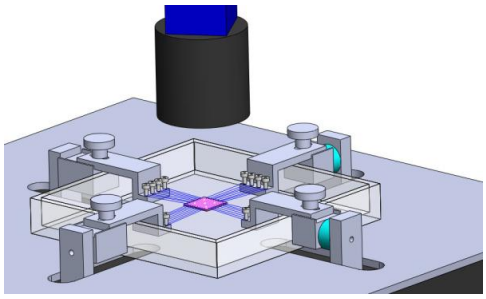
Constitutive models are necessary to predict the mechanical behavior of biological tissues. However, biological materials present challenges in constitutive modeling due to their complex mechanical behavior. Their oriented fibrous structures often exhibit pronounced mechanical anisotropy. Due to anisotropy, stress strain data generated from uniaxial tests cannot be used to extrapolate to generalized three-dimensional constitutive equations. Since biological tissues are generally considered incompressible, planar biaxial testing allows for a two-dimensional stress-state that can be used to characterize their mechanical properties and validate the constitutive models.

Biaxial stress-strain measurements on soft biological tissues are generally difficult to perform. Some of the challenges include: small specimen sizes; gripping the specimens; differing gripping techniques producing inconsistent results; identifying material axes; large specimen-to-specimen variability; time-dependent changes due to biological degradation; and achieving homogeneity of deformation within the specimen.

Biaxial testing of biological tissues is performed using thin specimens, which are either a membrane in its native form or a thin section prepared from a thick tissue slab. The specimen is mounted to the biaxial device in trampoline-like fashion using thin threads, which allows the edges to expand freely in the lateral direction. (ADMET will design other grip solutions depending on material and customer requirements.) Testing is generally performed with the specimen completely immersed in phosphate buffered normal saline (pH 7.4) at room or body (37◦ C) temperature, however, ADMET will accommodate testing that requires heating/cooling parameters. The central target region must be sufficiently small and located away from the outer edges to avoid the tethering effects. Thus, in the central target region the stress and strain field is generally considered homogeneous.

ADMET's planar biaxial testing system is designed specifically for soft materials and biological tissues. The two orthogonal actuators can be programmed to move independently or in a coordinated motion under force or deformation control. The testing system includes suture racks for gripping the specimen in trampoline like fashion. The suture racks are pinned to the moving crossheads for easy installation and removal. Another option is to attach several individual clips on the specimen and have the clips move independently to accommodate irregular elongation. Specimen baths and heating and cooling units for precise temperature control are also available. Various low force load cells and optical strain measurements provide accurate force-deformation data.





4. Suture Tensile Strength Test

A suture is a medical device that doctors use to hold skin, internal organs, blood vessels and all other tissues of the human body together, after they have been severed by injury or surgery. They must be strong enough to hold the tissue and flexible enough to be able to tie into knots easily.

Suture tensile strength determines where the suture can be used inside or outside of the body and for how long it is intended to remain. Sutures are absorbable or non-absorbable and in some cases, have needles attached.
Below we describe a typical suture tensile test and what type of equipment is needed to perform this test.

Types of Suture tests

- Standard tensile pull test.
- Knot pull tensile test- the knot is centered in between the grips.
- Creep test- Pull to a desired load and hold.

Procedure for straight pull

- Insert non-absorbable suture sample into pneumatic cord and yarn grips. The gauge length is usually 10 inches from grip to grip with a 2.5 inch grip separation. It is very important that the sample is lined up properly or it will impact the results of the test.
- Set profile to pull suture at desire speed to a desired load or until the sample breaks. We used 12 in/min.
- After sample breaks, the test stops.

Results
From the data we can tell the tensile strength and peak load of non-absorbable suture.

Suture sizes are defined by the United States Pharmacopeia (U.S.P.) Atraumatic needles are manufactured in all shapes for most sizes. The actual diameter of thread for a given U.S.P. size differs depending on the suture material class.

Many textile ASTM methods are used for thread testing, see ASTM D5034-95, ASTM D3787-89, ASTM D2256.

Video

5. Medical Hypodermic Needle Testing

Achieving a high standard of manufacturing quality for medical hypodermic needles is needed to ensure patient comfort and enable practitioners to accurately deploy and extract fluids with a syringe. During the product development process, needles can be subjected to flexure, tensile, and puncture tests to reach this required level of production consistency. Using ADMET testing equipment helps you perform these tests with accuracy while lowering your product development and manufacturing costs.

Flexure test: This measures the stiffness of the needle which helps predict how likely the needle is to permanently bend, or deform, when used. Commonly, the needle is loaded onto a 3-point-bend fixture (pictured below). The top of the fixture, attached to a load cell, pushes down on the center of the needle at a specified speed and distance to create the necessary amount of bend on the needle. The test data is then collected and calculations such as Young's Modulus are performed. For exact specifications on needle flexure tests, please refer to ASTM F1874 or the appropriate ASTM/ISO standard. These of tests normally require the following equipment:

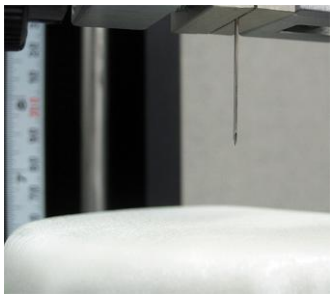
- A 3-point-bend fixture.
- A testing machine frame and load cell capable of applying enough downward force on the sample to create the required bend.
- A testing controller capable of controlling the frames actuator at the speed and distance required by the specification and gather test data to perform calculations such as Young's Modulus.

Tensile Test: This measures the fundamental integrity, or strength, of the needle which helps predict how the specimen will react to tensile forces and recognize weak points along the specimen. Commonly, the needle is secured at each end by a manual of pneumatic vice grip. Once the specimen is secured, the grip connected to the load and actuator is separated, at a specified rate, from the grip connected to the base of the frame until the needle breaks (rupture). For exact specifications on tension tests for hypodermic needles, please refer to ASTM A908 or the appropriate ASTM/ISO standard. These of tests normally require the following equipment:

- A pair of vice grips with appropriately serrated faces to prevent the needle from slipping.
- A machine frame and load cell capable of applying enough tensile force to bring the sample to a clean break.
- A testing controller capable of moving the grips at the specified rate, identify peak load, and record test data.

Puncture test: This tests the sharpness of the needle point and the uniformity of the needle tube by measuring the amount of force needed to puncture, penetrate, and extract the needle from tissue. The test procedure normally begins by securing the blunt end of the needle to a grip and load cell. The actuator, which holds the needle, is then moved to puncture, penetrate, and remove the needle from a fixture holding a stretched material designed to replicate tissue. For exact specifications on needle puncture tests, please refer to ASTM F2132 or the appropriate ASTM/ISO standard. These of tests normally require the following equipment:

- A grip capable of firmly securing the needle and a fixture to hold a stretched, tissue-like material.
- A machine frame providing the required amount of travel and a low capacity load cell capable of providing the required sensitivity for more complete data.
- A testing controller capable of moving the actuator at the specified rate and displaying graphical test results.

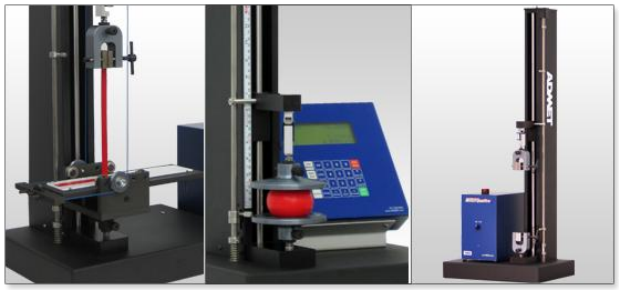


Additional Information

1. Testing Machines

eXpert 7600 Series

- Compact table-top design
- Perform tension, compression, peel and bend tests
- Test high elongation materials
- Exceeds ASTM and ISO standards for accuracy



eXpert 2600 Series

- Quiet, compact and low maintenance
- Perform tension, compression, peel and bend tests
- Test a wide range of load capacities and speeds
- Exceeds ASTM and ISO accuracy standards

Micro Mini Testing Systems

- Miniature design, fits in the palm of your hand
- Adaptable to micro scope stages
- Perform tension, compression and bend tests
- Capacities up to 5kN; Capable of milligram low force testing
- Speeds up to 500 mm/min

Torsion Testing Systems

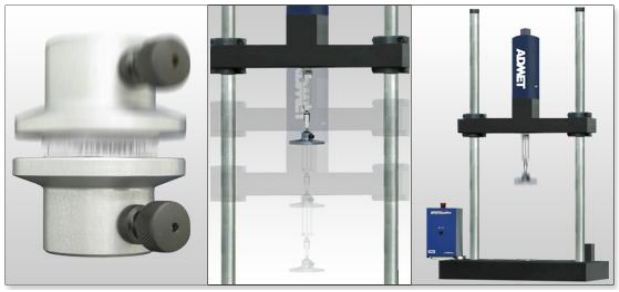
- Table-Top units available in vertical or horizontal orientations
- Speed up to 20 Hz
- Capacity: 5Nm - 300Nm (static), 5Nm - 25Nm (Fatigue)

Biaxial Testing Systems

- Tension/compression/torsion (TCT)
- Planar biaxial systems
- Ideal for simulating real-world conditions

Fatigue Testing Systems

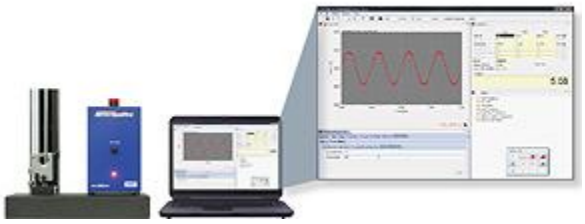
- Clean, quiet, and compact
- High accelerations, exceptional accuracy, and repeatability
- Servo hydraulic or electromechanical

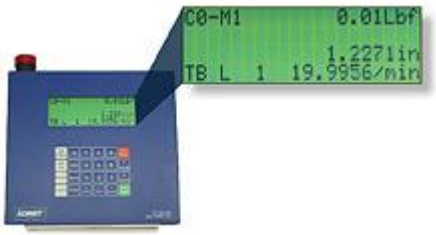


2. Testing Machine Controllers

All ADMET Testing Machines can be equipped with one of two closed loop servo controllers. MTESTQuattro®, our most advanced testing controller, is a PC-based unit that offers a wide range of flexibility in control, data acquisition, analysis, and reporting. The eP2 Digital Controller, a standalone touch panel unit, offers a balance between performance and simplicity. Both controllers feature 8 kHz servo update periods and programmable log rates to 1 kHz.

Controller	**MTESTQuattro**	**eP2**
Interface	PC Software	Touch Panel
Analysis	Extensive calculations library w/ built in ASTM/ISO Specification analysis.	Standard calculation package for basic testing requirements and QC testing.
Test Procedures	Use built-in or create an unlimited number of simple to complex procedures.	Save up to six test procedures in eP2.
Reporting	Store and organize all data. View and print user customizable test reports with chart and tables.	Post test, view current results on eP2 screen and send data to PC for reporting using optional GaugeSafe Software.





3. Useful Links and Contact Information

Testing News, Videos, and How to Guides
All ADMET Testing Systems
Grips and Fixtures

Phone: **800-667-3220**
Email: info@admet.com

www.ADMET.com